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Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852

Tuesday, December 28, 1999

Re: Docket # 97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products

To whom it may concern:

We are writing this letter in order to express our significant concerns about the proposed Food and Drug Administration rules regarding donor egg IVF. Specifically, our objection is to the proposed requirement that resultant embryos from a donor egg IVF cycle are frozen and quarantined for 6 months when the previously screened donors can then be re-tested for infectious diseases.

To begin with, we are not aware of any evidence throughout the literature to support the notion that oocytes (eggs), embryos, or isolated spermatoazoa (sperm cells) are, or can be, vectors of infectious diseases (such as HIV) in the process of IVF. It is true that semen carries a different, and appreciable risk for transmission of such diseases, thus the justification exists for cryopreservation of semen/sperm specimens for donor insemination procedures. However, this risk is only hypothetical with regards to isolated, washed sperm cells, eggs, and resultant embryos in egg donation cycles. It has not been demonstrated in any specific papers, and over the 21 years that IVF has been performed, no known transmission of HIV has ever occurred.

Aside from the lack of any obvious scientific justification for these proposals, several other clinical, economic, and psychological concerns also exist. Quarantining embryos would dramatically decrease the success rates for donor egg IVF, since all embryos would have to be frozen and transferred in a future frozen embryo cycle. In our institute for example, the success rate of frozen cycles is often less than half that of fresh cycles. Patients would thus, as a whole, need to undergo further cycles on average in order to conceive. This, coupled with the added costs of freezing, storing, thawing, and subsequently transferring the frozen embryos would drive the overall prices up exorbitantly for both the patients and insurance companies. In fact, the proposed recipient couple themselves may then also need to have repeat screening testing performed (since testing such as (eg.) baseline ultrasounds at the outset of the

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treatment cycle may not be valid six months later), thus further increasing health care costs. Additionally, the processes of freezing and thawing could result in the loss of many embryos, thus resulting in cancelled cycles, further increases in financial expenditures, and obvious psychological ramifications. Finally, as many of the recipient patients are older and would be forced to delay child bearing further, such restrictions could actually increase the health risks for these women, as well as unnecessarily exposing them to further stress, anxiety, and emotional strain.

In summary, for the reasons outlined above, we are clearly in objection to the proposed policy from the Food and Drug Administration of quarantining embryos resulting from donor egg IVF. In addition to the reasoning cited, it seems terribly unfair that we, as reproductive specialists, may be forced by such legislation to inform many unfortunate, and often desperate, couples that we can essentially help them achieve their lifelong dream only once every six months.

Should you have any further questions, please feel free to contact us at your convenience.

Sincerely yours,

M.D.

Suna Mahasin Qasim, M.D., F.A.C.O.G., Co-Director

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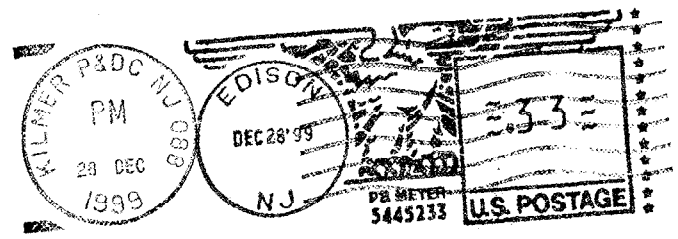

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